Docket No. 65814(46590) U.S. National Phase of PCT/JP2004/019758

Filed: Herewith

Horinouchi et al.

Page 5 of 10

**REMARKS** 

I. Support for the Amendments

Claims 1 and 6 have been amended. Support for the amendments to claims 1 and 6 can

be found in the original specification, including the Examples, and in the claims, including the

previous language of the claims. Additional support for amended claims 1 and 6 can be found,

e.g., from page 4, line 20, to page 7, line 23; from page 7, line 28, to page 8, line 5; on page 15,

lines 2-17; from page 15, line 32, to page 20, line 22; on page 22, lines 12-32; on page 24, lines

8-11; and in the Examples. No new matter has been added. Support for the amendments to the

claims can be found throughout the Japanese original of the specification and claims as filed.

No new matter is added by virtue of these amendments.

The Abstract has been amended to replace "comprises" and "comprising" with "includes"

and "including." No new matter is added by virtue of these amendments.

II. Status of the Claims

Claims 1-10 are presently in the application. Claims 1 and 6 have been amended.

III. The Examiner has Acknowledged the Priority Claim

Applicants thank the Examiner for acknowledging receipt of all certified copies of the

priority documents.

Docket No. 65814(46590)

U.S. National Phase of PCT/JP2004/019758

Filed: Herewith Horinouchi et al.

Page 6 of 10

VI. The Translation of the Priority Application

Applicants thank the Examiner for acknowledging the priority claim based on Japanese

Applications 2003-434151 (filed in Japan on December 26, 2003) and 2004-168849 (filed in

Japan on June 7, 2004).

Applicants submit herewith a certified translation of priority document Japanese Patent

Application 2004/168849 (filed in Japan on June 7, 2004), along with the verification of the

translation ("Translator's Declaration").

V. The Information Disclosure Statements

The Examiner has acknowledged the receipt of the Information Disclosure Statements

mailed June 23, 2006, and October 24, 2006. While the Examiner has returned the initialed

Form PTO/SB/08a/b (substitute for Form 1449) for the IDS mailed June 23, 2006, the initialed

Form PTO/SB/08a/b for the IDS mailed October 24, 2006, has not been returned.

Applicants respectfully request the return of the initialed Form PTO/SB/o8a/b for the IDS

mailed October 24, 2006.

VI. The Objection to the Abstract is Accommodated

The Examiner has objected to the Abstract with respect to the use of the words

"comprises" and "comprising." Applicants have amended the Abstract to replace these words

Docket No. 65814(46590)
U.S. National Phase of PCT/JP2004/019758
Filed: Herewith
Horinouchi et al.
Page 7 of 10

with, respectively, "includes" and "including." No new matter has been added by virtue of these amendments to the Abstract.

Applicants respectfully submit that the Abstract fulfills the requirements of MPEP §608.01(b).

## VII. The Rejection of Claims 1-10 under 35 U.S.C. §112, Second Paragraph, is Accommodated

The Examiner has rejected claims 1-10 under 35 U.S.C. §112, second paragraph (pp. 2-3). Applicants have amended claims 1 and 6.

## The Patent Office alleges:

On line 1 of claim 1, the phrase "lipidosis by a compound" is indefinite since it is not clear whether this means that the lipidosis is caused by or a direct result of the compound. On the last line of claim 1, the phrases "the index" and "the quantitative ratio of the two" lack antecedent basis. See this same problem in claim 6. In addition, the phrase "the quantitative ratio of the two" should be changed to —the quantitative ratio of (a): (b)--in order to provide further clarification. This same change should also be made in part (2) of claim 6.

In part (2) of claim 6, the recited "diagnosis" should be positively recited as a diagnosis of lipidosis or a disease related thereto in order to provide further clarification. [P. 2.]

Applicants have amended claims 1 and 6 in accordance with the Examiner's suggestions. Claims 2-5 and 7-10 are dependent on underlying claims 1 and 6, respectively, and the amendments to claims 1 and 6 apply respectively to these claims.

Applicants respectfully submit that claims 1-10 fulfill the requirements of 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance.

Docket No. 65814(46590)
U.S. National Phase of PCT/JP2004/019758
Filed: Herewith
Horinouchi et al.
Page 8 of 10

VIII. The Rejection of Claims 1-5 under 35 U.S.C. §102(a) for Alleged Anticipation by Mori is Traversed

The Examiner has rejected claims 1-5 under 35 U.S.C. §102(a) alleging anticipation by Mori et al (J. Toxicological Sci., 29(4) (October 2004); "Mori"). Applicants respectfully traverse the Examiner's rejection and submit that Mori does not anticipate the claims.

The Patent Office alleges, in pertinent part:

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The reference to Mori et al qualifies as prior art under 35 USC 102(a) since the authors of the article are different than the inventive entity of the instant application, and Applicants have not filed English language translations of the priority documents. [P. 4.]

Applicants submit herewith a certified English translation of the priority document

Japanese Application 2004-168849, which was filed in the Japanese Patent Office on June 7,

2004, prior to the October 2004 publication of Mori. (Applicants also submit herewith a

Translator's Declaration regarding the translation.) Applicants respectfully submit that, as
shown in the certified translation, the claimed inventions are fully disclosed in Japanese

Application 2004-168849, that they were therefore invented prior to the publication of Mori, and that Mori is not a prior art reference.

Applicants respectfully submit that the remaining claims 1-5 fulfill the requirements of 35 U.S.C. §102(a) and request the Examiner's reconsideration of these claims accordingly.

Docket No. 65814(46590) U.S. National Phase of PCT/JP2004/019758

Filed: Herewith Horinouchi et al. Page 9 of 10

XII. The Rejection of Claims 6-10 under 35 U.S.C. §103(a) for Alleged Obviousness over

Mori is Traversed

The Examiner has rejected claims 6-10 under 35 U.S.C. §103(a) alleging obviousness over Mori et al (J. Toxicological Sci., 29(4) (October 2004); "Mori"). Applicants respectfully traverse the Examiner's rejection and submit that Mori does not render the claims obvious.

As noted above, Applicants submit herewith a certified English translation of the priority document Japanese Application 2004-168849, which was filed in the Japanese Patent Office on June 7, 2004, prior to the October 2004 publication of Mori. (Applicants also submit herewith a Translator's Declaration regarding the translation.) Applicants respectfully submit that, as shown in the certified translation, the claimed inventions are fully disclosed in Japanese Application 2004-168849 and that Mori is not a prior art reference.

Applicants respectfully submit that the remaining claims 6-10 fulfill the requirements of 35 U.S.C. §103(a) and request the Examiner's reconsideration of these claims accordingly.

Docket No. 65814(46590) U.S. National Phase of PCT/JP2004/019758

Filed: Herewith Horinouchi et al.

Page 10 of 10

**CONCLUSION** 

In view of the foregoing amendments and remarks, the present application is respectfully

considered in condition for allowance. An early reconsideration and notice of allowance are

earnestly solicited.

It is believed that all outstanding rejections have been addressed by this submission and

that all the claims are in condition for allowance. If discussion of any amendment or remark

made herein would advance this important case to allowance, the Examiner is invited to call the

undersigned as soon as convenient.

It is believed that no extension of time is required. If an extension of time is required,

Applicants hereby request the Examiner to consider this a conditional petition for an extension of

time. Although it is not believed that any additional fee (in addition to the fee concurrently

submitted) is required to consider this submission, the Commissioner is hereby authorized to

charge our deposit account no. <u>04-1105</u> should any fee be deemed necessary.

Respectfully submitted,

Date: January 2, 2008

Kathryn A. Piffat, Ph.D. (Reg. No. 34,901)

Intellectual Property Practice Group of

EDWARDS ANGELL PALMER & DODGE, LLP

P.O. Box 55874 Boston, MA 02205 (617) 239-0100

BOS2\_649651.1